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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2018-0054]

Proposed Assisted Reproductive Technology (ART) Success Rates Reporting and Data Validation Procedures

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) requests comments on a plan to 1) revise the definition and characterization of Assisted Reproductive Technology (ART) success rates and 2) introduce clinic validation footnotes for the annual ART Fertility Clinic Success Rates Report. The footnotes will identify clinics that are selected by CDC to participate in the validation process of the National ART Surveillance System (NASS) data and that: 1) do participate, 2) do participate and have major data

discrepancies identified through this process, and/or 3) decline to participate in the data validation process. CDC requests comments on this plan in order to continue to ensure that the public has access to accurate and transparent data pursuant to the Fertility Clinic Success Rate and Certification Act of 1992.

DATES: Written comments must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0054 by any of the following methods:

- Federal eRulemaking Portal:
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Sara Crawford, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway N.E., MS F-74, Atlanta, Georgia 30341. Phone: (770) 488-6370. Email: artinfo@cdc.gov.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments

received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Sara Crawford, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway N.E., MS F-74, Atlanta, Georgia 30341. Phone: (770) 488-6370. Email: artinfo@cdc.gov.

SUPPLEMENTARY INFORMATION:

I. Success Rates

A. Background

Section 2(a) of Public Law 102-493 (42 U.S.C. 263a-1(a)), the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), requires that each assisted reproductive technology (ART) program report annually to the Secretary of the Department of Health and Human Services through the

Centers for Disease Control and Prevention (CDC) pregnancy success rates achieved through assisted reproductive technology. The FCSRCA also requires the CDC to annually publish and distribute to the public reported pregnancy success rates. According to the FCSRCA, the definitions of pregnancy success rates should be developed in consultation with appropriate consumer and professional organizations, should take into account the effect on success rates of age, diagnosis, and other significant factors, and should include the live birth rate per attempted ovarian stimulation procedure and the live birth rate per successful oocyte retrieval.

Specifics about the reporting process and requirements are described in "Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs" (80 FR 51811). Specifics about the definition and characterization of ART success rates were last described in "Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs" (69 FR 5548). Success rates for fresh, nondonor cycles were defined as: 1) the rate of pregnancy after completion of ART according to the number of all ovarian stimulation or monitoring procedures; 2) the rate of live birth after completion of ART according to the number of all ovarian stimulation or monitoring

procedures, the number of oocyte retrieval processes, and the number of embryo (or zygote or oocyte) transfer procedures; 3) the rate of singleton live birth after completion of ART according to the number of all ovarian stimulation or monitoring procedures and the number of embryo (or zygote or oocyte) transfer procedures. Success rates for cycles using thawed embryos and cycles using donor oocytes or embryos were defined as: 4) the rate of live birth after completion of ART according to the number of embryo (or zygote or oocyte) transfer procedures; 5) the rate of singleton live birth after completion of ART according to the number of embryo (or zygote or oocyte) transfer procedures.

Effective for reporting year 2017, CDC is proposing substantial changes to the definition and characterization of ART success rates due to changes in clinical practice and more variation in treatment options, including improvements in cryopreservation resulting in more segmentation of typical treatment cycles. The field of ART is moving toward the calculation and reporting of cumulative success rates where data collection systems can collect successes over all embryo transfers from a single oocyte retrieval or across several oocyte retrievals and embryo transfers. After consultation with consumer and

professional organizations with expertise in ART, CDC will begin cumulative ART success rates reporting in reporting year 2017. The ART success rates described in this Federal Register notice shall replace those previously described in 2004.

B. ART Procedures among Patients Using Their Own Oocytes

ART success rates for ART procedures among all patients using their own eggs will be defined as:

1. The rate of live birth or singleton live birth resulting from the transfer of oocytes retrieved from the patient in the year prior to the reporting year or from the transfer of embryos created from oocytes retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, transfer procedures must have started within 12 months of the start of the retrieval procedure. Oocytes must have been retrieved in the year prior to the reporting year in order to allow for a full year to perform transfers of the retrieved oocytes (either in the prior reporting year or in the current reporting year). The live

birth rate and singleton live birth rate will be presented according to the number of:

- a. All ovarian stimulation or monitoring procedures started from the year prior to the reporting year with the intent to retrieve oocytes from the patient.
- b. All ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient in which at least one oocyte was retrieved.
- c. All transfer procedures of at least one oocyte retrieved from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

- 2. The number of ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes

from the patient presented according to the number of:

- a. Live births resulting from all transfers of at least one oocyte retrieved from the patient in the year prior to the reporting year, or transfers of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

Other rates for ART procedures among all patients using their own eggs may be defined as-

3. The rate of cancellation, implantation, pregnancy, live birth, singleton live birth, multiple live birth, twin live birth, triplet or higher order live birth, preterm live birth, low birthweight live birth or term, normal birthweight and singleton live birth resulting from the transfer of oocytes retrieved from the patient in the year prior to the reporting year or the transfer of embryos created from oocytes retrieved from the patient in the year

prior to the reporting year. For the purpose of this definition, transfer procedures must have started within 12 months of the start of the retrieval procedure. These other rates may be presented according to the number of:

- a. All ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient.
- b. All ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient in which at least one oocyte was retrieved.
- c. All transfer procedures of at least one oocyte retrieved from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

- d. All first, second, third, or more transfer procedures after retrieval of at least one oocyte from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

Rates for ART procedures among new ART patients (i.e. patients that have never had a prior ART cycle ever) using their own oocytes will be defined as-

4. The rate of live birth resulting from the transfer of oocytes or embryos from all first intended oocyte retrievals presented according to the number of:
 - a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures. For the purpose of this definition, the retrieval procedure must have

started in the year prior to the reporting year.

5. The rate of live birth resulting from the transfer of oocytes or embryos from all first or second intended oocyte retrievals presented according to the number of:

a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures. For the purpose of this definition, the retrieval procedure must have started in the year prior to the reporting year.

6. The rate of live birth resulting from the transfer of oocytes or embryos from all intended oocyte retrievals presented according to the number of:

a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures. For the purpose of this definition, the retrieval procedure must have

started in the year prior to the reporting year.

7. The number of ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient presented according to the number of:

a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures.

8. The number of transfer procedures of at least one oocyte retrieved from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year presented according to the number of:

a. Ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient. For the purpose of this definition, egg or embryo transfer procedures must have

started within 12 months of the start of the retrieval procedure. Also, ART patients must have reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures.

C. ART Procedures among Patients Using Oocytes or Embryos from a Donor

Success rates for ART procedures among patients using oocytes or embryos from a donor will be defined as-

9. The rate of live birth or singleton live birth presented according to the number of:

- a. Transfer procedures of at least one donor egg, embryo created from a donor egg, or donated embryo started in the current reporting year.

Other rates for ART procedures among patients using oocytes or embryos from a donor may also be defined as-

10. The rate of cancellation, implantation, pregnancy, live birth, singleton live birth, multiple live birth, twin live birth, triplet or

higher order live birth, preterm live birth, low birthweight live birth, or term, normal birthweight and singleton live birth presented according to the number of:

- a. ART procedures to prepare a patient (recipient) for the transfer of at least one donor egg, embryo created from a donor egg, or donated embryo, started in the current reporting year.
- b. Transfer procedures of at least one donor egg, embryo created from a donor egg, or donated embryo started in the current reporting year.

D. ART Procedures among All Patients and All Cycle Types

ART reporting may also include:

- 11. The number, average number or percentage of ART procedures or ART patients with certain characteristics, such as:
 - a. Patient characteristics (e.g. patient age or reason for ART).
 - b. ART procedure characteristics (e.g. type of treatment (fertility preservation, short term banking, in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian

transfer), stimulation protocol, source of the oocytes or embryos (patient or donor), the state of the oocytes or embryos (fresh or frozen), the intent of the procedure, the use of prenatal genetic diagnosis or screening, the use of intracytoplasmic sperm injection, the use of assisted hatching, the use of a gestational carrier, the stage of the embryo at transfer, or the number of embryos transferred).

All ART patient and procedure characteristics, ART success rates, and other rates for patients using their own oocytes as well as for patients using oocytes or embryos from a donor may be stratified by factors thought to influence the outcome of an ART procedure.

12. Factors for stratification may include:

- a. Characteristics of the ART patient such as patient age or reason for ART.
- b. Characteristics of the ART procedure such as type of treatment (fertility preservation, short term banking, in vitro fertilization, gamete intrafallopian transfer, zygote

intrafallopian transfer), stimulation protocol, the source of the oocytes or embryos (patient or donor), the state of the oocytes or embryos (fresh or frozen), the intent of the procedure, the use of prenatal genetic diagnosis or screening, the use of intracytoplasmic sperm injection, the use of assisted hatching, the use of a gestational carrier, the stage of the embryo at transfer, or the number of embryos transferred.

Section II. Validation

A description of external validation of clinic data conducted annually as a part of the ART surveillance program is described in "Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs" (80 FR 51811). This notice explains, "If major data discrepancies are identified during data validation (e.g., lack of supporting information for pregnancy outcomes, underreporting cycles, etc.), CDC may re-select these ART programs for data validation during the following reporting year(s) to assess corrections of identified data errors."

Additionally, effective as of the 2019 reporting year, CDC will include a footnote in the annual *ART Fertility Clinic Success Rates Report* to identify clinics that are selected by CDC to participate in the validation process of the NASS data and that: 1) do participate, 2) do participate and have major data discrepancies identified through this process, and/or 3) decline to participate in the data validation process. CDC will include this footnote pending the availability of the necessary resources. This footnote is a new addition to the annual *ART Fertility Clinic Success Rates Report*. Pursuant to the Fertility Clinic Success Rate and Certification Act of 1992, the CDC is mandated to publish the clinic-specific success rates reported by each clinic. These footnotes will help to alert the public if there is evidence that the reported success rates may be of questionable quality, thereby increasing the transparency of the data reporting process.

If a clinic is selected to participate in the NASS data validation process and does participate, the following footnote will be added:

This clinic was visited for validation of (*insert: reporting year*) data. See Appendix A for additional information.

If a clinic is selected to participate in the NASS data validation process, does participate, and major data discrepancies are identified for either the number of reported ART cycles or the ART pregnancy outcome, the following footnote will be added:

This clinic was visited for validation of (*insert: reporting year*) data. Major data discrepancies were identified for (*insert: "the number of reported cycles" or "the pregnancy outcomes" or "the number of reported cycles and the pregnancy outcomes"*). See Appendix A for additional information.

If a clinic is selected to participate in the NASS data validation process and declines to participate, the following footnote will be added:

This clinic was selected for validation of (*insert: reporting year*) data, but declined to participate. See Appendix A for additional information.

Appendix A of the *ART Fertility Clinic Success Rates Report* contains information about the validation of NASS data, including methods used for clinic selection, and displays aggregate validation results. Aggregate validation results include national discrepancy rates; clinic-specific discrepancy rates are not reported. Any footnote added to a clinic's success rates page in the *ART Fertility Clinic Success Rates Report* will appear only for the reporting year that the clinic was selected for validation; it will be removed the following reporting year.

Dated: May 24, 2018.

Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.

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